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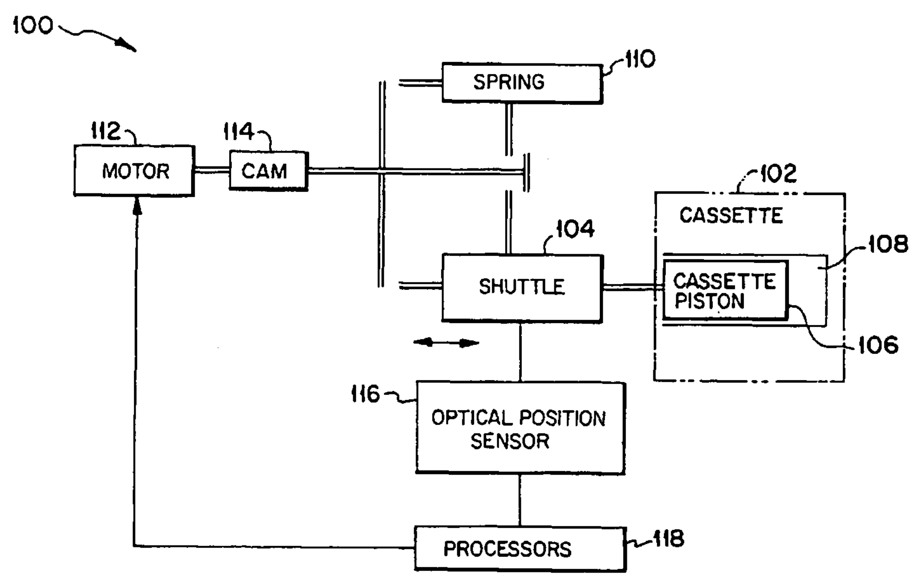
(54) Title: CONTROLLED FORCE FLUID DELIVERY SYSTEM



(57) Abstract: A controlled force fluid delivery system which provides fluid delivery with continuity over a wide range of flow rate. The system sets the force provided by an energy storage device, e.g. a spring and the opening of system outlet valve in response to a low volume due command. Specifically at a flow rate, the controlled force is decreased and/or the outlet valve of the system closes before the fluid flow reaches stable velocity whereas at a high flow rate the controlled force is increased and/or the outlet valve does not close until the fluid stops flowing. The system also reduces fluid flow rate variation in part by adjusting the timing and the level of opening and closing the outlet valve, and the speed of pumping the fluid out of system central cassette chamber.

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Controlled Force Fluid Delivery System

Field of the Invention

[0001] The present invention relates to a fluid delivery system, especially a unique controlled force fluid delivery system capable of displacing fluid at a wide range of flow rates.

Background of the Invention

[0002] Infusion pumps are generally well known in the medical field for administering medications to patients over an extended time period. Typical medications may include antibiotics, anesthetics, analgesics, cardiovascular drugs, chemotherapy agents, electrolytes, narcotics, whole blood and blood products, etc. Infusion pumps are typically designed for a particular clinical application: e.g., many pumps are designed principally for use on the hospital general floor; other pumps are designed for pediatric use; other pumps are designed for critical care use; still other pumps are designed for home healthcare use, etc. Also, infusion pumps are typically designed for either large volume fluid delivery (say from one liter bags or bottles of diluted medication) or for small volume fluid delivery (typically from syringes filled with up to 60mL of undiluted medication), but not for both. Such a wide variety of specialized pumps require hospitals and healthcare facilities to maintain a large diverse inventory of pumps, to ensure staff training is current on all pumps, and to provide a wide variety of service training. This diversity of specialized pumps leads to increased cost, increased capital investment, and increased medication administration errors.

[0003] Therefore, there exists a need for a mechanism to control fluid delivery in a manner such that a single infusion pump can fully satisfy the drug infusion needs of multiple hospital and healthcare applications (including home healthcare), can deliver small volume as well as large volume doses over a wide range of required flow rates, and can provide small size and weight, power-efficient, cost-efficient implementation. The infusion pump described in this invention in conjunction with a cassette, such as the one disclosed in U. S. Patent Application No. 60/216,658 entitled "Cassette," filed concurrently herewith, to Carlisle, Costa, Holmes, Kirkman, Thompson and Semler, the contents of which are incorporated herein by reference, allows a drug infusion system to achieve these objectives.

Summary of the Invention

[0004] The invention is based on the discovery that a system using a controlled force for fluid delivery can employ inertial effects of the fluid system and provide continuing fluid displacement over a wide range of flow rates. The present invention provides a controlled force fluid delivery system, especially a system with a modifiable force provided by an energy storage device and modified by feedback of fluid displacement. In particular, the system sets the amount of controlled force and the opening of system outlet valve in response to a flow rate command. At a low flow rate, the controlled force is decreased and/or the outlet valve of the system closes before the fluid flow reaches stable velocity whereas at a high flow rate the controlled force is increased and/or the outlet valve does not close until the fluid stops flowing. The system also reduces fluid flow rate variation in part by adjusting the timing and the level of opening and closing the outlet valve, and the speed of pumping the fluid out of system central cassette chamber.

[0005] The invention and its other advantages will be apparent from the following detailed description, and from the claims.

Brief Description of the Drawings

[0006] These and other objects and advantages of the invention will become more apparent and more readily appreciated from the following exemplary embodiment of the invention taken in combination with the accompanying drawings, of which:

[0007] FIG. 1 is a diagram illustrating the fluid delivery system.

[0008] FIG. 2 is a diagram illustrating a cross-sectional view of the cassette assembly of an infusion pump.

[0009] FIGS. 3(a)-3(c) are block diagrams illustrating three opening states of an outlet valve.

Detailed Description of Exemplary Embodiment

[0010] One of the applications of the controlled force fluid delivery system is an infusion pump. FIG. 1 shows a block diagram of one embodiment of the present invention. The fluid delivery system 100 includes a cassette assembly 102 and a shuttle mechanism 104. A suitable cassette assembly is described in patent application number 60/216,658, filed concurrently

herewith, entitled "Cassette" to Carlisle, Costa, Holmes, Kirkman, Thompson and Semler, the entire contents of which are incorporated herein by reference. Within the cassette assembly 102 is a cassette piston 106 and a cassette central chamber 108. An energy storage device, such as a spring 110, biases the shuttle mechanism 104, which is connected to the cassette piston 106. Piston 106 slides freely to draw fluid into the cassette central chamber 108 and pump fluid out of central chamber 108. A motor 112 is activated in one direction to draw the cassette piston 106 out of cassette central chamber 108 via cam 114 and shuttle 104. When the cassette piston 106 is withdrawn to the desired extent, shuttle 104 disengages from cam 114 and motor 112, so that spring 110 pushes the cassette piston 106 into the cassette central chamber 108 via shuttle 104 to apply positive pressure to the fluid in the cassette central chamber 108. The shuttle mechanism 104 is also operably linked to an optical position sensor 116. A suitable position sensor is described in patent application number 60/217,885, filed concurrently herewith entitled "Optical Position Sensor and Position Determination Method", to Carlisle, Kaplan and Kirkman, the entire contents of which are incorporated herein by reference. A processor 118 is connected to motor 112 and the position sensor 116.

[0011] FIG. 2 shows a block diagram illustrating a cross-sectional view of a cassette assembly 102. The cassette assembly 102 contains an inlet valve 200, an outlet valve 210, a cassette central chamber 108, and a cassette piston 106. Cassette piston 106 is connected to shuttle 104. The outlet valve 210 is operated by an actuator 212. Actuator 212 is driven by cam 114 connected to motor 112.

[0012] In operation, the motor 112 is activated in one direction to withdraw the cassette piston 106 against the force of spring 110 via cam 114, creating a relative vacuum in the cassette central chamber 108 and pulling fluid through a one-way passive inlet valve 200 into the cassette central chamber 108. During this fill stroke, the pressure in the cassette central chamber 108 is negative, *e.g.*, between 0 and –10 psi. The amount of negative pressure depends on the withdrawal speed of the piston, fluid resistance, fluid viscosity, etc. The cassette piston can be withdrawn to different positions or fill levels depending on the intended displacement volume of the fluid. In one embodiment, the minimum fluid volume pumped into the cassette central chamber 108 during each fill stroke is about 50 μl and the maximum fluid volume is about 500 μl. In another embodiment, a turbo mode is used to increase the maximum fluid volume by further withdrawing the cassette piston 106 to let the fluid fill up the entire cassette central chamber 108.

[0013] Once the cassette piston 106 has been withdrawn, cam 114 disengages from the shuttle 104, enabling the spring mechanism 110 to urge shuttle 104 to drive piston 106 into the cassette central chamber 108. The pressure in the chamber then moves from a negative value through zero to a positive value. The one-way passive inlet valve 200 is now fully closed. The positive pressure in the cassette central chamber 108 is typically between +2 and +7 psi depending on the spring force applied to the cassette piston 106 through the shuttle 104 which is directly related to the length of the withdrawal stroke, *e.g.*, the further the withdrawal stroke the stronger the spring force.

[0014] Upon finishing withdrawal of the cassette piston 106, cam 114 disengages from the shuttle 104 and engages actuator 212 so that the motor 112 operates the outlet valve 210 through actuator 212. The outlet valve 210 opens incrementally, partially or fully as shown in FIGS 3(a) –3(c) depending on the amount of activation force received from motor 112 through actuator 212. When the outlet valve 210 opens incrementally as shown in FIG 3(a), the outlet valve 210 opens in a pulse mode, *e.g.*, it opens on and off, and closes before the fluid finishes its acceleration. The outlet valve 210 is in a nudge mode when it opens partially as shown in FIG 3(b) or fully as shown in FIG 3(c). When the outlet valve 210 is in a nudge mode, it opens continuously and does not close before the fluid reaches stable velocity. The fluid flow through a partially opened outlet valve 210 can be precisely metered out and is controlled by the distance between the tapered surface and the valve seat. Once the outlet valve 210 is fully opened, the fluid flow through the outlet valve 210 is controlled by the distance between valve stem 310 and valve-housing seat 320, although fluid flow is usually dominated by higher resistance in the circuit, such as an IV needle or catheter.

[0015] According to the present invention, the force that generates the positive pressure in the cassette central chamber is controlled based on the length of the withdrawal stroke and is directly related to shuttle position. Thus, the force is modifiable in response to various conditions of a fluid delivery system, *e.g.*, desired flow rate, volume of fluid displacement, and flow continuity. For example, the processor 118 receives a flow rate command and feedback position changes provided by the position sensor 116 and directs motor 112 to cock the spring 110 to various degrees thus modify the spring force applied to the cassette piston 106.

[0016] In one mode, the force generating the positive pressure is decreased in response to a desired low flow rate. Specifically the processor 118 directs the motor 112 to conduct a partial

withdrawal stroke, *e.g.,* less than full length, therefore generating less than the full amount of the spring force, thus pumping less fluid out of the cassette central chamber 108.

[0017] In another mode, if the volume of fluid due the patient for the next opening of the outlet valve 210 is less than 40 µl, the processor 118 directs the motor 112 to provide a corresponding spring force and/or directs the outlet valve 210 to open in a pulse mode. The duration of the pulse is modifiable based on the position change of the cassette piston 106 which represents the volume of fluid displacement. For example, the amount of time that the motor 112 is energized to open the outlet valve 210 is adjusted on an ongoing basis based on the position change provided by the position sensor 116 to the processor 118, so that the cracking point of the outlet valve 210 is reached. At a low flow rate, the inertial component of the fluid flow is significant because the fluid flow is constrained mainly by the acceleration of the moving mass of the system instead of the resistance of the pathway. That is, the fluid does not achieve a steady state flow rate instantly. Instead, the mass of all moving components (e.g., the fluid, piston 106 and shuttle 104) must be accelerated by the force of spring 110. This dynamic adjustment accommodates a wide tolerance in mechanics and fluidics.

[0018] In yet another mode, if the volume of fluid due the patient for the next opening of the outlet valve 210 is greater than 40 µl, the processor 118 directs the motor 112 to provide a corresponding spring force and/or directs the outlet valve 210 to be opened partially, *e.g.,* in a nudge mode so that fluid is metered out through the outlet valve 210. The amount of partial opening of the outlet valve 210 depends on the duration of motor 112 actuation through actuator 212, which is controlled by processor 118 based on the position change received from the optical position sensor 116.

[0019] In still another mode, the processor 118 of the system adjusts the force and/or the outlet valve 210 to provide a desired low flow rate with a desired flow continuity. Specifically, at a low flow rate, *e.g.,* less than 5ml/hr, the system of the present invention dispenses fluid at intervals no longer than about 8 seconds.

[0020] Similarly, the force that generates the positive pressure in the cassette central chamber can also be increased to provide continuing fluid delivery at a high flow rate. For example, increasing the length of the withdrawal stroke increases the spring force applied to the cassette piston, thus pumping more fluid out of the central chamber. In one mode, the outlet valve 210 is not closed until the fluid stops flowing. As spring 110 causes the central chamber 108 to empty, the force of the spring, and therefore, the pressure within the central chamber 108,

decreases. Ignoring the effects of momentum, this continues until the pressure in the central chamber 108 equals the pressure downstream of outlet valve 210. However at high flow rate, the moving mass has momentum which allows the fluid to continue traveling for a short time even after the pressure differential between the cassette central chamber 108 and the downstream of the outlet valve 210 has decreased to zero. Thus to maximize the fluid flow, the outlet valve 210 is kept open even after the pressure is equalized between the cassette central chamber 108 and the downstream of the outlet valve 210 and is closed only after the fluid stops flowing.

[0021] Another feature of the present invention reduces fluid flow rate variation, *e.g.,* pulsatile flow rate changes. In one embodiment, the processor 118 adjusts the timing of opening and closing the outlet valve 210 to reduce fluid flow rate variation. Specifically, the processor 118 adjusts the amount of time the motor 112 is energized to open the outlet valve 210 before being shut off over a period of time to allow the outlet valve 210 to return to its normally closed position. For example, during fluid delivery the processor 118 directs the motor 112 to open the outlet valve 210 for a period of time, then directs a brake force on the motor 112. Once a brake force is applied the outlet valve 210 is kept open for a period of time until the shuttle 104, *i.e.,* the cassette piston 106 reaches a targeted position. The period of time in which the motor 112 is energized is adjusted by the processor 118 based on the maximum fluid flow rate during an empty or outlet cycle. In one embodiment, the processor adjusts the outlet valve 210 based on the targeted maximum shuttle speed which can be readily measured by the position sensor 116. Usually the targeted maximum shuttle speed is 10 mm/sec during a nudge mode outlet cycle for a controlled force fluid delivery system of the present invention.

[0022] The processor 118 adjusts the shuttle speed by adjusting the level of openness of the outlet valve 210 based on the minimum time period between the digital interrupts recorded by the optical position sensor 116. Normally, the minimum time period between the digital interrupts is about 8 msec. If it is less than 8 msec, then the shuttle is moving too fast and the outlet valve is opened to a lesser degree or closed to a larger degree; on the other hand if it is more than 8 msec, then the shuttle is moving too slowly and the maximum force or power to pump fluid out of the central chamber is increased.

[0023] Another feature of the invention includes providing a steady power output of the motor 112. In one embodiment, pulse width modulation (PWM) value is modulated as f(Vb1), where the power input to the motor 112 is a function of the main battery voltage Vb1. Over a

period of time, as the main battery voltage decreases the PWM is adjusted to achieve a steady power output from the motor 112.

Other Embodiments

[0024] Although several exemplary embodiments of this invention have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiment without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following claims.

What is claimed is:

1. A fluid delivery system comprising:

a central chamber with an inlet valve and an outlet valve;

a piston assembly moving in and out of the central chamber;

a force source connected to the piston assembly, wherein the force source generates a force to move the assembly in and out of the central chamber thereby moving fluid out of and into the central chamber;

a position sensor connected to the piston assembly, wherein the position sensor determines a position change of the piston assembly; and

a processor connected to the position sensor, and the force source, wherein the processor receives the position change of the piston assembly, modifies the amount and duration of force generated by the force source, and controls the opening of the outlet valve.

2. The system of claim 1, wherein the force source comprises a motor which generates a negative pressure in the central chamber and pumps fluid into the central chamber via the piston assembly, and an energy storage device which receives energy from the motor and employs the stored energy to generate a positive pressure in the central chamber and pump fluid out of the central chamber via the piston assembly, wherein the processor controls the amount of energy stored in the energy storage device.

3. The system of claim 2, wherein the energy storage device is a spring.

4. The system of claim 2, wherein the motor simultaneously generates the negative pressure and stores energy in the energy storage device.

5. The system of claim 4, wherein the processor determines a flow rate and directs the motor to generate a negative pressure based on the flow rate.

6. The system of claim 2, wherein the energy storage device generates a positive pressure when it is disconnected from the motor.

7. The system of claim 2, wherein the motor opens the outlet valve.

8. The system of claim 2, wherein the motor opens the outlet valve in a pulsed mode.

9. The system of claim 2, wherein the processor directs the motor to open the outlet valve in a pulsed mode in response to a low volume due command.

10. The system of claim 9, wherein the low volume due command is less than 40 μl.

11. The system of claim 1, wherein the processor causes the outlet valve to open in a pulse mode in response to a low volume due command.

12. The system of claim 11, wherein the low volume due command is less than 40 μl.

13. The system of claim 1, wherein the processor causes the outlet valve to close before the fluid finishes acceleration to a stable velocity.

14. The system of claim 13, wherein the processor causes the outlet valve to close before the fluid finishes acceleration to a stable velocity in response to a low volume due command.

15. The system of claim 1, wherein the processor causes the outlet valve to close after the fluid stops flowing.

16. The system of claim 1, wherein the processor causes the outlet valve to open when the assembly is moved into the central chamber.

17. The system of claim 1, wherein the processor causes the outlet valve to open in a nudge mode in response to a low volume due command.

18. The system of claim 2, wherein the processor directs the motor to open the outlet valve in a nudge mode in response to a low volume due command.

19. The system of claim 1, wherein the processor causes the outlet valve to open in a period of time in response to a low volume due command.

20. The system of claim 19, wherein the processor causes the outlet valve to open in a period of time in response to a predetermined speed of the piston assembly.

21. The system of claim 1, wherein the processor causes the outlet valve to close in response to a position change of the piston assembly.

22. The system of claim 21, wherein the processor causes the outlet valve to close in response to a predetermined position change of the piston assembly.

23. The system of claim 1, wherein the processor causes the outlet valve to close in a period of time.

24. The system of claim 23, wherein the processor causes the outlet valve to close in a period of time in response to a detected speed of the piston assembly.

25. The system of claim 2, wherein the processor directs the motor to close the outlet valve in a period of time in response to a predetermined position change of the piston assembly.

26. The system of claim 2, wherein the processor directs the motor to close the outlet valve in a period of time in response to a detected speed of the piston assembly.

27. The system of claim 1, wherein the outlet valve is opened by an amount in response to a low volume due command.

28. The system of claim 1, wherein the outlet valve is opened by an amount determined by a detected speed of the piston assembly.

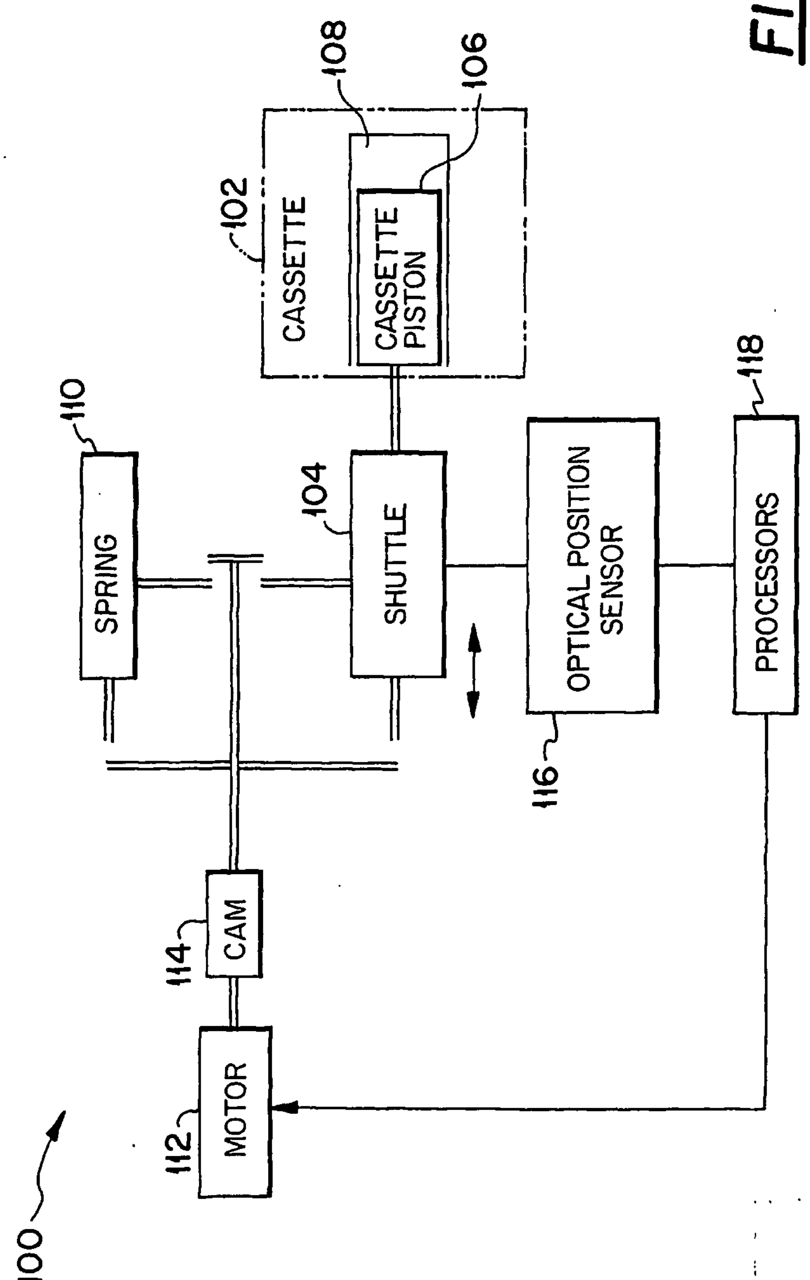
CASSETTE
CASSETTE PISTON
SPRING
SHUTTLE
OPTICAL POSITION SENSOR
PROCESSORS
CAM
MOTOR
100
102
104
106
108
110
112
114
116
118

FIG. 1

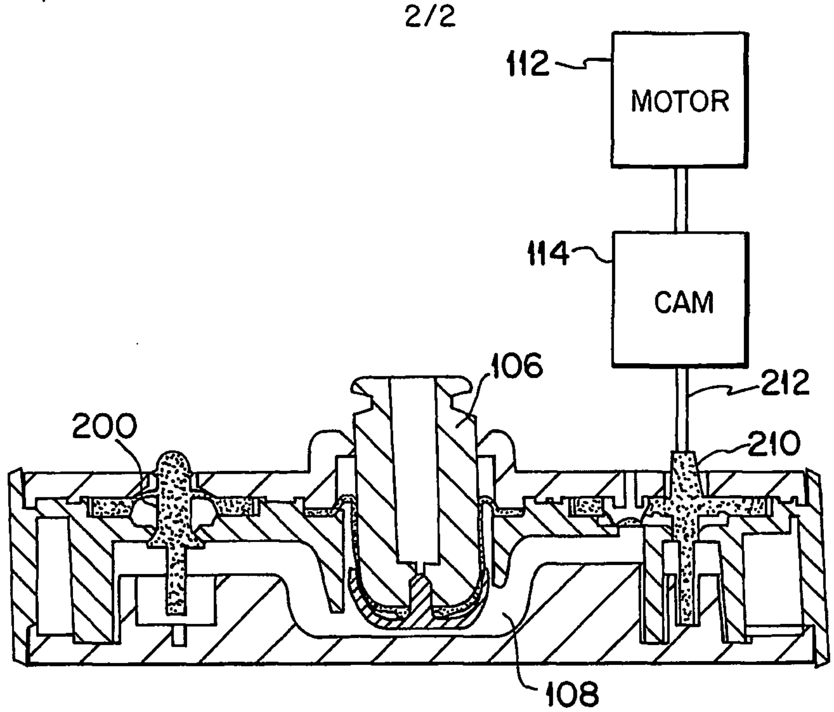

FIG. 2

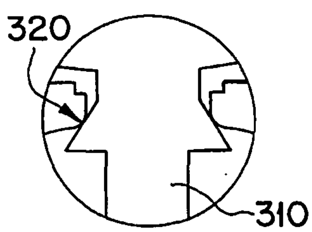

FIG. 3a

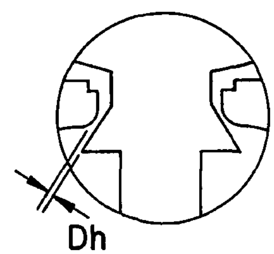

FIG. 3b

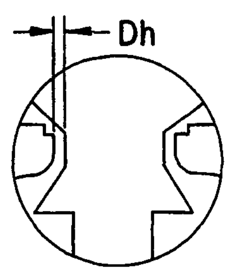

FIG. 3c